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10/622,725	07/18/2003	Frank Butaric	CRD-0836 DIV I	2936
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PHILIP S. JOHNSON			MILLER, CHERYL L	
JOHNSON & JOHNSON				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,725	<b>Applicant(s)</b> BUTARIC ET AL.
	<b>Examiner</b> CHERYL MILLER	<b>Art Unit</b> 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 May 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-6 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: *Attachments 1-3*

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2009 has been entered.

### ***Response to Arguments***

Applicant's arguments filed April 13, 2009 have been fully considered but they are not persuasive. The applicant has argued that none of the applied reference disclose sinusoidal connector rings having at least one of two peaks or two valleys between circumferentially adjacent cells. The examiner disagrees. Each of the applied rejection has the claimed peaks and valleys, this is clearly shown in the attachments. Also, it is noted that although peaks and valley are shown in applicant's figures, applicant's specification does not specify which side are peaks and which side are valleys. Thus when applicant recites "peaks" for example, it is unclear which bends applicant is referring to. Also the language, "between circumferentially adjacent diamond shaped cells" is broad to cover all peaks and valley that span the maximum width of two diamonds (that is, it is not limited to the space inbetween the diamond connects to the sinusoidal ring).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 line 11 recites, "there are at least one of two peaks or two valleys between each circumferentially adjacent diamond shaped cell" which is considered new matter-exactly two peaks or exactly two valleys are not found between adjacent diamonds. Details of applicant's stent are shown in figures 4 and 8. Rings or rows of diamond cells are shown to alternate with sinusoidal rings. Between circumferentially adjacent diamonds, there appears to be between 2-6 peaks and 3-7 valleys OR 3-7 peaks and 2-6 valleys (depending on what one considers a peak and a valley-applicant's specification does not specify which are peaks and which are valleys and whether "inbetween diamonds" refers to the distance spanned by two diamonds-max width OR distance inbetween interconnections of the diamonds with the ring). For example, if the peaks face the proximal end of the stent and the valleys face the distal end of the stent, sometimes two peaks exist between circumferentially adjacent diamonds and sometimes three peaks exist between circumferentially adjacent diamonds (not always two). Claims 2-6 depend upon claim 1 and inherit all problems associated with the claim. See attachment 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al.

(US 5,122,154, cited previously) in view of Chevillon et al. (US 2003/0065378 A1, cited previously). Referring to claim 1, Rhodes discloses a stent-graft (fig.3) comprising a hollow substantially cylindrical radially expandable stent (all 30's) having a plurality of interconnected struts (32) forming diamonds, the diamonds connected cylindrically into hoops (see figures; each ring 30 is a hoop shaped element), and a graft member (28) attached to the stent (30's), the graft member comprising longitudinally directed pleats (28A). Rhodes discloses a stent graft substantially as claimed, however Rhodes discloses a plurality of individual stents along the length of the graft instead of a single unitary stent. Chevillon teaches in the same field of stent-grafts, the use of a single unitary stent (5', 5"; fig.10, 11) having the stent configuration claimed (see attachment 2; which shows two peaks between diamonds; the width of two diamonds is spanned by two or three peaks or valleys of the adjacent sinusoidal ring) as an alternative to a plurality of individual stents (5; fig.1) along a length of a graft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Rhodes stent-graft having a plurality of stents, with Chevillon's teaching of using a unitary stent as an alternative to a plurality along a graft in order to provide a stent-graft of a different stent design still serving the function of supporting the vessel. Stents of various structures are well known in the art, including linked, separated, and unitary stents. It would have been obvious to substitute one stent for the other, with the use of Rhodes graft as it would be common sense Rhodes pleated graft could be used with stents of different designs such as those illustrated by Chevillon.

Referring to claim 2, Rhodes discloses the graft (28) attached to an exterior of the stents (col.6 line 66-col.7 line 1).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevillon et al. (US 2003/00653378 A1, cited previously) in view of Lunn (US 5,476,506, cited previously). Referring to claim 1, Chevillon discloses a stent-graft (fig.10, 11) comprising a single hollow substantially cylindrical radially expandable stent (5', 5") having the structure claimed (fig.10, 11; attachment 2 shows two or three peaks or valleys spanning the width of two circumferentially adjacent diamonds) and a graft member (3) attached to the stent (5', 5"), the stent being covered by the entire length of the graft (figures). Chevillon discloses the stent-graft substantially as claimed, however does not disclose longitudinal pleats on the graft. Lunn teaches in the same field of stent-grafts, the use of longitudinal pleats (22, 24; col.3, lines 10-15; fig.1, 2) on grafts in order to provide the graft with increased capability for expansion (col.3, lines 42-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Chevillon's stent-graft with Lunn's teaching of longitudinal pleats on grafts, in order to provide a stent-graft with increased expansion capability, such that the stent-graft may be better tailored to the size of the patient's vessel. Longitudinal pleats on vascular graft structures are well known in the art see for example as evidence Rhodes US 5,122,154 and Trecony US 5,653,745, both cited previously.

Referring to claims 2 and 4-6, Chevillon discloses the graft (3) to cover an exterior surface of the stent (5', 5"; see fig.10, 11), the graft formed of dacron ( P0056), and the stent to be self-expanding made of superelastic nickel titanium (P0061).

Referring to claim 3, Chevillon discloses attached of the stent (5") to the graft (3) by an attachment means (7), however does disclose the attachment means to be a staple (Chevillon discloses sutures instead of staples). Lunn teaches in the same field of stent graft's the use of staples as a common attachment means (col.5, lines 10-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Chevillon's in view of Lunn's stent-graft with Lunn's teaching of staples as a common attachment means, in order to provide a stent-graft attachment by an alternate means (staple instead of suture-both known to be common means for attachment in the art).

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. (US 5,693,085, cited previously) in view Lunn (US 5,476,506, cited previously) and Milo (US 6,206,911 B1, cited previously). Referring to claim 1, Buirge discloses a single stent (10; 40; fig.1 or 3; and stents incorporated by references in US 4,954,126 and US 4,776,337 for example), and a graft (12), the stent (10) being covered by the entire length of the graft (12; fig.1) and the stent shown to have various configuration and discloses to be any suitable stent design (col.3, lines 36-60; col.6, lines 65-67). Buirge discloses the stent-graft substantially as claimed, however does not disclose the specific stent structure claimed or the graft to have longitudinal pleats. Milo discloses an alternate stent design (see figure 3) having diamond cells (35) arranged in a cylinder (cylindrical elements) spaced by sinusoidal rings (43), two peaks at least between circumferentially adjacent diamonds (see fig.3, attachment 3). Stents of various structures are well known in the art. It would have been obvious to substitute one stent for the other. Lunn teaches in the same field of stent-grafts, the use of longitudinal pleats (22, 24) on grafts (10) in order to provide an increased expansion capability (col.3, lines 10-16, 37-47). It

would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Buirge's stent-graft, with Milo's teaching of an alternate stent design and with Lunn's teaching of longitudinal pleats in order to provide a stent-graft with increased capability to expand to the desired diameter of a patient's vessel. Longitudinal pleats on vascular graft structures are well known in the art see for example as evidence Rhodes US 5,122,154 and Trescony US 5,653,745, both cited previously. Stent structures with diamond cells and sinusoidal rings are also well known in the art, see Chouinard (US 6,585,758; fig.6, 7), Vargas (US 6,652,541 B1; fig.7), Culombo (US 6,190,405 B1; fig.1) for further evidence of such commonly known stent designs.

Referring to claims 2, 5, and 6, Buirge discloses the graft (12) to be attached to the exterior of the stent (fig.1), and the stent to be self-expanding nickel-titanium (col.3, lines 36-55).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/  
Examiner, Art Unit 3738  
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